Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

Manufacturer Of Controlled Substances

Notice Of Application

IRIX Manufacturing, Inc.

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on January 18, 2013, IRIX Manufacturing, Inc., 309

Delaware Street, Greenville, South Carolina 29605, made application to the Drug Enforcement

Administration (DEA) to be registered as a bulk manufacturer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance as API for clinical trials.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR § 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement

Administration, Office of Diversion Control, Federal Register Representative (ODL),8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION].

Joseph T. Rannazzisi Deputy Assistant Administrator Office of Diversion Control Drug Enforcement Administration

DATED: August 5, 2013

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